

10/565418

PATENT Case No. ITR0065YP

IAP6 Rec'd PCT/PTO 23 JAN 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Monaci, et al.

Serial No. To Be Assigned

Filed: January 23, 2006

For: SYNTHETIC GENE ENCODING HUMAN EPIDERMAL  
GROWTH FACTOR 2/NEU ANTIGEN AND USES  
THEREOF

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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DATE OF DEPOSIT January 23 2006

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By \_\_\_\_\_ Date \_\_\_\_\_

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## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- the attached information is filed within three months of the filing date of the captioned case.
- the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Alycia A. Finnegan  
Attorney For Applicant(s)

Reg. No. 48,878

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-2583

Date: 1/23/06

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE</b></p> <p><b>STATEMENT BY APPLICANT</b></p> <p><i>(use as many sheets as necessary)</i></p>				<b>COMPLETE IF KNOWN</b>	
				<b>Application Number</b>	To Be Assigned <b>10/565418</b>
				<b>Filing Date</b>	January 23, 2006
				<b>First Named Inventor</b>	Monaci, et al.
				<b>Group Art Unit</b>	
				<b>Examiner Name</b>	
Sheet	1	of	3	Attorney Docket Number	ITR0065YP

**Examiner  
Signature** \_\_\_\_\_ **Date  
Considered** \_\_\_\_\_

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet

2

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<b>COMPLETE IF KNOWN</b>	
Application Number	To Be Assigned
Filing Date	January 23, 2006
First Named Inventor	Monaci, et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number ITR0065YP	

107305418

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bargmann, et al., "The neu oncogene encodes an epidermal growth factor receptor-related protein", Nature, Vol. 319, 16 January 1986, pp. 226-230.
		Ben-Levy, et al., "A single autophosphorylation site confers oncogenicity to the Neu/ErbB-2 receptor and enables coupling to the MAP kinase pathway", EMBO Journal, Vol. 13, No. 14, pp. 3302-3311, 1994.
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		Disbrow, et al., "Codon optimization of the HPV-16 E5 gene enhances protein expression", Virology, Vol. 311, pp. 105-114, 2003.
		Disis, et al., "Cancer Vaccines Targeting the Her2/neu Oncogenic Protein", Seminars in Oncology, Vol. 28, No. 6, Suppl. 18, December 2001, pp. 12-20.
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		Disis, et al., "Her-2/neu Protein: A Target for Antigen-Specific Immunotherapy of Human Cancer", Advances in Cancer Research, Vol. 71, pp. 343-371, 1997.
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		Ioannides, et al., "Cytotoxic T Cells Isolated from Ovarian Malignant Ascites Recognize a Peptide Derived from the Her-2/neu Proto-oncogene", Cellular Immunology, Vol. 151, pp. 225-235, 1993.
		King, et al., "Amplification of a Novel v-erbB-Related Gene in a Human Mammary Carcinoma", Science, Vol. 229, No. 4717, pp. 974-976, 1985.
		Klapper, et al., "Biochemical and Clinical Implications of the ErbB/HER Signaling Network of Growth Factor Receptors", Adv. Cancer Res., Vol. 77, pp. 25-79, 2000.

Examiner Signature	Date Considered
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				10/565418	
<b>INFORMATION DISCLOSURE</b>				<b>Application Number</b>	To Be Assigned
<b>STATEMENT BY APPLICANT</b>				<b>Filing Date</b>	January 23, 2006
(use as many sheets as necessary)				<b>First Named Inventor</b>	Monaci, et al.
				<b>Group Art Unit</b>	
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Sheet	3	of	3	Attorney Docket Number	ITR0065YP

<b>NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Leder, et al., "Enhancement of Capsid Gene Expression: Preparing the Human Papillomavirus Type 16 Major Structural Gene L1 for DNA Vaccination Purposes", J. of Virol., Vol. 75, No. 19, pp. 9201-9209, Oct. 2001.
		Lustgarten, et al., "Identification of Her-2/Neu CTL Epitopes Using Double Transgenic Mice Expressing HLA-A2.1 and Human CD.8", Human Immunology, Vol. 52, pp. 109-118, 1997.
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		Nakamura, et al., "Codon usage tabulated from the international DNA sequence databases: Its status 1999", Nucleic Acids Research, Vol. 27, No. 1, pp. 292, 1999.
		Peoples, et al., "T lymphocytes that infiltrate tumors and atherosclerotic plaques produce heparin-binding epidermal growth factor-like growth factor and basic fibroblast growth factor: A potential pathologic role", PNAS, USA, Vol. 92, pp. 6547-6551, 1995.
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		Yoshino, et al., "HER2/neu-derived Peptides Are Shared Antigens among Human Non-Small Cell Lung Cancer and Ovarian Cancer", Cancer Research, Vol. 54, pp. 3387-3390, 1994.

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